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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,428	03/24/2006	Peter Anthony Campochiaro	010804-22190200	4757

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EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,428	CAMPOCHIARO ET AL.	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2,3,6-8,10,12,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,9,11 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/05/2008; 08/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of pigment epithelium-derived growth factor (PDGF) as the species of therapeutic agent in the reply filed on 04/18/2008 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4 and 6 have been amended. Claims 13-20 are new.

Claims 2, 3, 6, 7, 8, 10, 12, 19, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1, 4, 5, 9, 11, and 13-18 are under examination.

Specification

2. The disclosure is objected to because of the following informalities: this application contains sequence disclosures (p. 23) that are encompassed by the definitions for nucleotide sequences set forth in 37 CFR 1.821 (a)(1) and (d). However, the specification fails to comply with the requirements of 37 CFR 1.821 (a)(1) and (d), because the sequence identifiers, preceded by SEQ ID NO are missing.

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 4, 5, 9, 11, and 13-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 47, 48, and 62-68 of copending Application No. 10/508,580. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants. Specifically, both sets of claims encompass ocular gene therapy by using viral vectors encoding PDGF. It is noted that, although the application claims do not recite an adenoviral or a lentiviral vectors, it would have been obvious to one of skill in the art to modify the application claims by using such vectors to achieve the predictable result of delivering a protein to the retina of a subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 4, 5, 9, 11, and 13-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-15, and 58 of copending Application No. 11/377,857. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants. Specifically, both sets of claims encompass ocular gene therapy by using viral vectors encoding PDGF. It is noted that, although the application claims do not recite an adenoviral or a lentiviral vectors, it would have been obvious to one of skill in the art to modify the application claims by using such vectors to achieve the predictable result of delivering a protein to the retina of a subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 4, 5, 9, 11, and 13-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 11/938,562. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants. Specifically, both sets of claims encompass ocular gene therapy by using viral vectors encoding PDGF. It is noted that, although the application claims do not recite an adenoviral or a lentiviral vectors, it would have been obvious to one of skill in the art

to modify the application claims by using such vectors to achieve the predictable result of delivering a protein to the retina of a subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 4, 5, 9, 11, and 13-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 27, 28, 30-32, 38-41, 45-47, and 51-62 of copending Application No. 10/080,797. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants. Specifically, both sets of claims encompass ocular gene therapy by using viral vectors encoding a protein. It is noted that the broad genus of "a protein-encoding nucleic acid" recited in the instant claim 1 is anticipated by the vectors encoding endostatin recited in the application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 4, 5, 9, 11, and 13-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/526,127. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants. Specifically, both sets of claims encompass ocular gene therapy by using viral vectors encoding a protein. It is noted that the broad genus of "a protein-encoding

nucleic acid" recited in the instant claim 1 is anticipated by the vectors encoding endostatin recited in the application claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 4, 5, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuthbertson et al. (U.S. Patent No. 5,827,702).

Cuthbertson et al. teach a method of delivering a therapeutic protein to the retina of a subject, the method comprising administering a viral vector comprising a nucleic acid encoding the therapeutic protein (claim 1); the viral vector could be an adenoviral, adeno-associated, or retroviral vector (claims 4, 5, and 13-15) (column 2, lines 55-60; column 3, lines 17-33; column 4, lines 18-20; column 5, lines 34-59; column 7, lines 3-28, claims 1-5). Since Cuthbertson et al. teach all claim limitations, the claimed invention is anticipated by the above-cited art.

11. Claims 1, 4, 5, 13, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (J. Cell. Physiol., August 2001, 188: 253-263).

Mori et al. teach a method of delivering PDGF to the retina of a subject, the method comprising administering a viral vector comprising a nucleic acid encoding PDGF (claims 1 and 18), wherein the viral vector is an adenoviral vector (claims 4, 5, and 13) (Abstract; p. 254, column 2; p. 255, column 1; p. 256, columns 1 and 2; p. 256, column 2). Since Mori et al. teach all claim limitations, the claimed invention is anticipated by the above-cited art.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 4, 5, 9, 11, and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al., in view of both Cuthbertson et al. and Metharom et al. (J. Gene Med., 2000, 2: 175-185).

The teachings of Mori et al. are applied as above for claims 1, 4, 5, 13, and 18. Mori et al. do not teach adeno-associated or bovine lentiviral vectors (claims 4, 9, 11, and 14-17). However, at the time the invention was made, these vectors were known and widely used in the art of gene therapy. For example, Cuthbertson et al. teach using adeno-associated vectors to deliver PDGF to the retina of a subject (column 3, lines 25-32; column 5, lines 35-38) and Metharom et al. teach gene therapy by using a bovine lentiviral vector (Abstract). It would have been obvious to one of skill in the art, at the

time the invention was made, to modify the method of Mori et al. by using an adeno-associated vector or a bovine lentiviral vector to achieve the predictable result of delivering PDGF to the retina. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

14. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Examiner, Art Unit 1633